



#3  
PCT  
DT07 Rec'd PCT/PTO 15 DEC 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Masayuki NAKAMURA et al. : Docket No. 2004\_1561A

Serial No. 10/509,253 : Group Art Unit **Not Yet Assigned**

Filed October 25, 2004 : Examiner **Not Yet Assigned**

HYDROXYMORPHOLINONE DERIVATIVE  
AND MEDICINAL USE THEREOF  
[Corresponding to PCT/JP03/03910  
Filed March 27, 2003]

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- each U.S. Patent and U.S. Patent application publication;
- each reference previously cited in the international application PCT/\_\_\_\_\_; and/or
- each reference previously cited in prior parent application Serial No. \_\_\_\_\_.

1a.  This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

- 1b.  This Information Disclosure Statement is submitted  
after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:  
(1)  the certification of paragraph 2 below is provided, **or**  
(2)  the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c.  This Information Disclosure Statement is submitted:  
after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:  
**the certification of paragraph 2 below is provided, and**  
**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified
- a.  that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
  - b.  that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3.  Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a.  a full or partial English language translation submitted herewith,
  - b.  a foreign patent office search report (in the English language) submitted herewith,
  - c.  the concise explanation contained in the specification of the present application at page,
  - d.  the concise explanation set forth in the attached English language abstract,
  - e.  the concise explanation set forth below or on a separate sheet attached to the reference:
5.  A foreign patent office search report citing one or more of the references is enclosed.
6.  Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Masayuki NAKAMURA et al.

By Warren M. Cheek  
Warren M. Cheek, Jr.  
Registration No. 33,367  
Attorney for Applicants

WMC/dlk  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
December 15, 2004

## INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (*modified*)ATTY DOCKET NO.  
2004\_1561ASERIAL NO.  
10/509,253U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: December 15, 2004

P E  
DEC 15 2004  
U.S. PATENT & TRADEMARK OFFICEAPPLICANT  
Masayuki NAKAMURA et al.FILING DATE  
October 25, 2004

GROUP

## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL |    | DOCUMENT NUMBER | DATE   | NAME           | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|----|-----------------|--------|----------------|-------|----------|----------------------------|
|                   | AA | 6,103,720       | 8/2000 | Lubisch et al. |       |          |                            |
|                   | AB | 6,057,290       | 5/2000 | Fukiage et al. |       |          |                            |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE   | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
|--|----|-----------------|--------|---------|-------|----------|--------------------|
|  | AC | 0 641 563       | 3/1995 | EP      |       |          |                    |
|  | AD | 6-29229         | 1/1987 | JP      |       |          | translation        |
|  | AE |                 |        |         |       |          |                    |

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |  |
|--|----|--|
|  | AF | A. Arcelli et al., "Unusual Ammonolysis of a Secondary Amide Assisted by Unsubstituted Vicinal Amide Group", Tetrahedron, Vol. 52, No. 11, pp. 4141-4148, 1996.  |
|  | AG | S. V. Ley et al., "A New Route to Butane-1,2-diacetals and the Development of Alternative Substitution Patterns to Facilitate Differential Protection of the Products", Synlett., No. 11, pp. 1793-1795, 1996. |
|  | AH | K. K. W. Wang et al., "Calpain Inhibition: An Overview of its Therapeutic Potential", Trends in Pharmacological Sciences, Vol. 15, pp. 412-419, November 1994.   |
|  | AI | M. Azuma et al., "Cysteine Protease Inhibitor E64 Reduces the Rate of Formation of Selenite Cataract in the Whole Animal", Current Eye Research, Vol. 10, No. 7, pp. 657-666, 1991.                            |
|  | AJ | C. Crawford et al., "The Design of Peptidyl Diazomethane Inhibitors to Distinguish Between the Cysteine Proteinases Calpain II, Cathepsin L and Cathepsin B", Biochem. J., Vol. 253, pp. 751-758, 1988.        |
|  | AK | H. Angliker et al., "Inactivation of Calpain by Peptidyl Fluoromethyl Ketones", J. Med. Chem., Vol. 35, pp. 216-220, 1992.   |
|  | AL |  |

EXAMINER

DATE CONSIDERED